UNITED STATES
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In re Application of	:	
HIGHFIELD et al.	:	
Serial No.: 09/664,363	:	DECISION ON PETITION
Filed: 18 September 2000	:	
Attorney Case No: 2035-38	:	

This is in response to applicants' alternative petition filed 20 September 2001, for review of the restriction requirement set forth on 20 April 2001 as Paper No. 4 in the above-identified application under the provisions of 37 CFR 1.181.

BACKGROUND

The examiner set forth the following restriction requirement under 35 U.S.C. 121 in Paper No. 4.

I. *Claims 1-6, 19 and 20, drawn to a subcombination PT-NANBH viral polypeptide and method of using the polypeptide, classified in class 424, subclass 228.1 .*

II. *Claims 7-8, 19 and 20, drawn to a combination PT-NANBH viral polypeptide and a method of using the polypeptide, classified in 424, subclass 205.1.*

Upon election of Group II, Applicant is additionally required to elect one polypeptide to be examined on the merits. This requirement is not to be construed as a requirement for an election of species, since each of the polypeptides recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

(1). The polypeptide encoded by SEQ.ID. NO.5 and SEQ. ID. NO. 3.

(2). The polypeptide encoded by SEQ.ID. NO.5 and SEQ. ID. NO. 4.

III. Claims 9-13, drawn to a DNA sequence encoding the subcombination PT-NANBH viral polypeptide and a method for using the DNA sequence as a vector to transform a cell line, classified in 536, subclass 23.72.

IV. Claim 14, drawn to an antibody against a subcombination PT-NANBH viral polypeptide, classified in 424, subclass 139.1.

V. Claim 15, drawn to a method for detecting PT-NANBH viral nucleic acids, classified in 204, subclass 469.

VI. Claim 16, drawn to a kit for detecting PT-NANB viral nucleic acids, classified in 435, subclass 975.

VII. Claim 17, drawn to a method for detecting PT-NANBH viral antigen or antibody and a kit used by the method, classified in 435, subclass 7.1.

VIII. Claim 18, drawn to a kit for detecting PT-NANB viral antigen or antibody, classified in 435, subclass 975.

Upon election of Group I, III-VIII, Applicant is additionally required to elect a single sequence to be examined on the merits. This requirement is not to be construed as a requirement for an election of species, since each of the polypeptide recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

a). Sequence of the polypeptide is SEQ. ID. NO. 3.

b). Sequence of the polypeptide is SEQ. ID. NO. 4.

c). Sequence of the polypeptide is SEQ. ID. NO. 5.

d). Sequence of the polypeptide is SEQ. ID. NO. 18.

e). Sequence of the polypeptide is SEQ. ID. NO. 19.

f). Sequence of the polypeptide is SEQ ID. NO. 20.

g). Sequence of the polypeptide is SEQ. ID. NO. 21.

h). Sequence of the polypeptide is SEQ. ID. NO. 22.

The examiner reasoned that each of the polypeptide molecules recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

In the election filed 20 September 2001, Applicants elected Group III, claims 9-13 and SEQ ID NO: 21 with traverse. The traverse was on the grounds that the election of a single sequence is inappropriate as that MPEP 2434 states that the Official Gazette Notice dated 19 November 1996, entitled "Examination of Patent Applications Containing Nucleotide Sequences," requires examination in most cases of up to 10 independent and

distinct sequences. Applicant requests examination of SEQ ID NO: (a)-(h) within Group III.

In the Office Action mailed 27 November 2001, as Paper No 7, the examiner considered the traversal and maintained that each of the sequences constitutes a distinct invention. The examiner further reasoned that searching for each of the elected profiles is not limited to only one sequence but includes all the limitations complied with it. Searching for those sequences which have at least 90% homology to SEQ ID NO: 21, as required by the claim limitations, causes a significant time consuming search of both in house databases and commercial databases. The restriction requirement was made final. Claims 9-13 were examined within the scope of SEQ ID NO: 21. Claims 1-8 and 14-20 were withdrawn from examination.

In the Alternative Petition filed 20 September 2001, (which was filed prior to a Final requirement by the examiner, and therefore premature) Applicants again argued that the MPEP 2434 and the O.G. Notice require an examination of up to ten sequences in most cases and that requiring applicants to elect one sequence places a financial burden on applicants to file additional applications.

DISCUSSION

These arguments have been considered carefully and found to be not persuasive for the following reasons. The Official Gazette Notice dated 19 November 1996, is directed to the examination of patent applications containing distinct nucleotide sequences. The Official Gazette Notice is silent concerning the examination of up to ten distinct polypeptide sequences. Similarly, the Official Gazette Notice is silent concerning the examination of nucleic acid molecules that encode up to ten distinct polypeptide molecules.

The elected invention, Group III, is directed to DNA that is described not in terms of distinct polynucleotide sequences, but rather in terms of specific polypeptide sequences encoded by such. The examination of the claimed DNA sequences would not solely require a search of nucleic acid databases, but would also require a search of the polypeptide databases using the elected polypeptide sequence SEQ ID NO: 21. Additional searches of nucleic acid sequences generated by a back-translation of the elected polypeptide sequence may also be required. In order to examine more than one DNA sequence, as claimed, the Office would be required to search more than one polypeptide sequence. As such, the burden placed on the Office does not allow for examination of nucleic acids encoding more than one patentably distinct polypeptide molecule. Nor does the Official Gazette Notice or MPEP 2434 require examination of polynucleotide sequences that encode up to ten distinct polypeptide sequences. The restriction requirement between the groups and between the polypeptide molecules was proper.

DECISION

Applicants' petition is **DENIED** for the reasons set forth above.

Applicants are under obligation to properly respond to the Office Action mailed 27 November 2001, within the time period set therein or as extendable under the provisions of 37 CFR 1.136(a).

Any request for reconsideration of this decision must be by way of a renewed petition and must be filed within TWO MONTHS of the date of mailing of this decision in order to be considered timely.

Should there be any questions with respect to this decision, please contact Special Program Examiner Julie Burke, Ph.D. by letter addressed to the Director, Technology Center 1600, Washington DC 20231. Alternatively, SPRE Burke can be reached by telephone at (703) 308-7553 or by facsimile transmission at (703) 305-7230.

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